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14   **UNITED STATES DISTRICT COURT**

15   **CENTRAL DISTRICT OF CALIFORNIA – WESTERN DIVISION**

16

17 NEUROGRAFIX, a California   Case No. 10-CV-1990 MRP (RZx)
corporation; WASHINGTON
18 RESEARCH FOUNDATION, a not-for-   [Assigned to The Honorable Mariana
profit Washington corporation,   R. Pfaelzer]
19
Plaintiffs,   **PLAINTIFFS' OPPOSITION TO
20   SIEMENS' MOTION FOR
vs.   PARTIAL SUMMARY
21   JUDGMENT OF
INDEFINITENESS OF
22 SIEMENS MEDICAL SOLUTIONS   "CONSPICUITY" IN CLAIMS 1, 3,
USA, INC., a Delaware corporation; and 7, 11, 12, 18, AND THEIR
23 SIEMENS AKTIENGESELLSCHAFT, a   ASSERTED DEPENDENT
German Corporation,   CLAIMS IN U.S. PATENT NO.
24   5,560,360**
Defendants.
25
26   First Amended Complaint Filed:
July 30, 2010
27

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**PLAINTIFFS' OPPOSITION TO SIEMENS' MOTION FOR PARTIAL SUMMARY JUDGMENT OF
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**PLAINTIFFS' OPPOSITION TO SIEMENS' MOTION FOR PARTIAL SUMMARY JUDGMENT OF
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Plaintiffs NeuroGrafix and Washington Research Foundation (collectively,
"NeuroGrafix") submit this response to Defendants' Motion for Partial Summary
Judgment of Indefiniteness of "Conspicuity" in Claims 1, 3, 7, 11, 12, 18, and
Their Asserted Dependent Claims in U.S. Patent No. 5,560,360 (the "Motion").

I.   INTRODUCTION.

The '360 patent expressly teaches to one of ordinary skill in the art how to
calculate conspicuity. The Court has already rejected Siemens' first argument to
render the "conspicuity" term indefinite for failing to provide a formula for
calculating conspicuity. Now, Siemens argues that the "conspicuity" term is
indefinite because the regions of interest to use in the conspicuity calculation are
ambiguous and indefinite. Similar to Siemens' first argument, the Court should
reject this argument because the '360 patent specifically teaches a person of
ordinary skill in the art how to select the regions of interest.

Preliminarily, although Siemens raised the issue and the Court requested
more information as a result, Siemens no longer disputes that the '360 patent
teaches how to identify nerve in an MR image. It is undisputed that a nerve can
usually be identified using gross anatomy and the surroundings shown in the MR
image. If that fails, it is also undisputed that the '360 patent teaches that the nerve
can also be identified using the fascicle pattern and/or diffusion weighting and fat
suppression techniques.

In order to perform the conspicuity calculation disclosed by the '360 patent,
a person of ordinary skill in the art must select a region of interest representing a
nerve and a region of interest representing the appropriate non-neural tissue. With
respect to selecting a region of interest of the nerve, the '360 patent expressly
discloses using a thresholding process to select the entire nerve. Ex. 4 at 28:2-
28:7; *see also id.* at 21:55-57, 30:65-67. The thresholding process described by the
'360 patent uses a standard tool built into DICOM image viewers. A person of

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ordinary skill in the art need only select a relatively bright pixel in known nerve tissue.
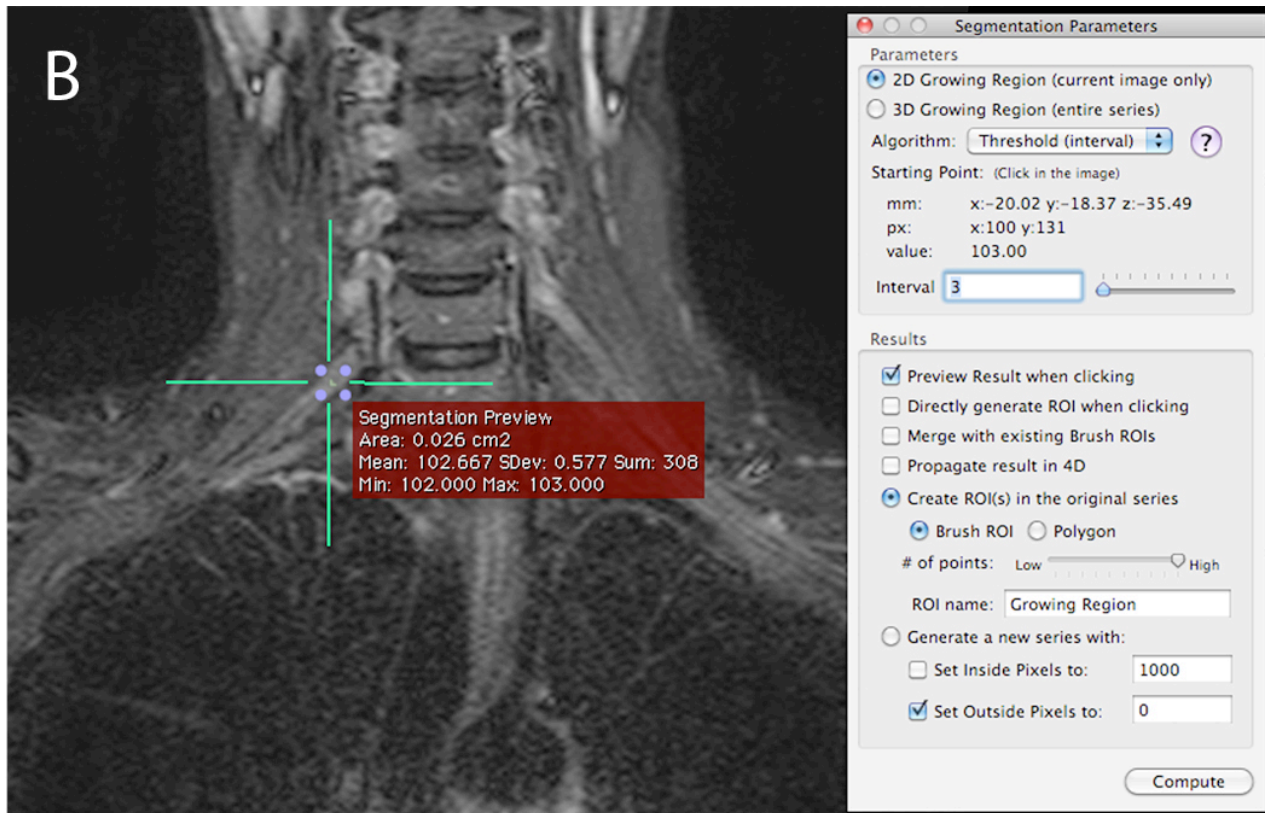
As the threshold level is lowered, more of the nerve is selected. The appropriate threshold level is therefore the level right before the region grows to include non-neural tissue (which is determined by gross anatomy). Contrary to Siemens' argument, this method of selecting the nerve region of interest is both definite and repeatable.

The selection of the region of interest for the non-neural tissue is similarly definite and repeatable. Claim 18 of the '360 patent requires selecting "any adjacent non-neural tissue." In light of the teachings of the '360 patent, Dr. Brant-Zawadzki, Executive Medical Director of the Neurosciences Institute at Hoag Memorial Hospital in Newport Beach, California and a practicing diagnostic radiologist for 35 years, testified that one of ordinary skill in the art would know to select the brightest adjacent non-neural tissue to perform the conspicuity calculation. This is also consistent with the statements of the inventors in the file

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history distinguishing an image in the prior art because the nerve was much darker than adjacent fat tissue. A person of ordinary skill in the art would not be confused as to the non-neural tissue to select for claim 18.

For the remaining claims (1, 3, 7, 11 and 12), the '360 patent also expressly teaches the non-neural tissue to use in the conspicuity analysis. In particular, the '360 patent expressly discloses to use the non-neural tissue in an approximately 2 centimeter ellipsoid surrounding the nerve. Unlike claim 18, the language of these claims requires that all of the non-neural tissue be selecting. The red and green regions of interest shown below illustrate the resulting selection of the region of interest for claims 1, 3, 7, 11 and 12.

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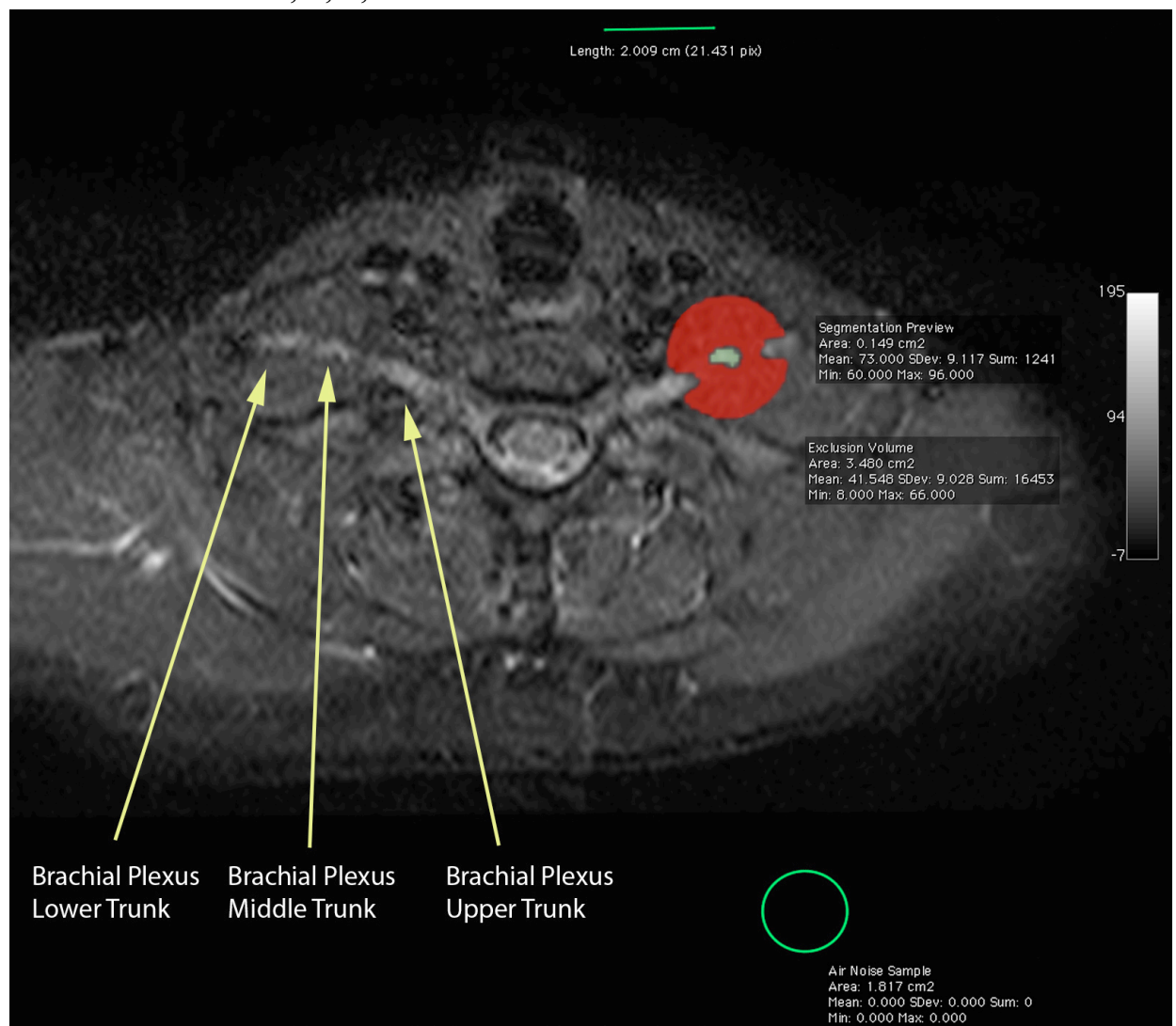
The '360 patent therefore teaches, to one of ordinary skill in the art, the method to use for selecting regions of interest to use in the conspicuity calculation. Siemens has failed to satisfy its burden to prove its argument by clear and convincing evidence.   Dr. Bryan does not perform conspicuity calculations consistent with the '360 patent.   And, Siemens' reliance on the calculations performed by Dr. Filler is also irrelevant because, when viewed in the context of his report, it is clear that Dr. Filler did not intend to perform a formal conspicuity calculation.   Instead, he provided the images and calculation to illustrate the problem with Dr. Moseley's opinions.

Siemens' Motion should be denied.

II.   APPLICABLE LEGAL STANDARD.

It is well established that "proof of indefiniteness must meet an exacting standard." *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244 (Fed. Cir. 2008). A patent claim is indefinite only if the moving party can show by clear and convincing evidence that a claim is "insolubly ambiguous." *Star Sci., Inc. v. R.J. Reynolds Tobacco Co.*, No. 2010-1183, 2011 U.S. App. LEXIS 17826, at *19 (Fed. Cir. Aug. 26, 2011) (slip. op.) (Ex. 1).[1] The alleged ambiguity of a claim is determined from the perspective of one skilled in the art, including all of the requisite knowledge of one skill in the art. *See AllVoice Computing PLC v. Nuance Commc'ns, Inc.*, 504 F.3d 1236, 1240 (Fed. Cir. 2007). A claim is definite "even when discerning the meaning is a formidable [task] and the conclusion may be one over which reasonable persons will disagree." *Source Search Tech., LLC v. Lendingtree, LLC*, 588 F.3d 1063, 1076 (Fed. Cir. 2009) (citing *Exon Research & Eng'g Co. v. United States*, 256 F.3d 1371, 1375 (Fed. Cir. 2001)). "In light of [the] presumption [of validity] . . . close questions of indefiniteness in litigation

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[1] Exhibits 1-14 referenced herein are attached to the Declaration of Andrew D. Weiss; Exhibits 15-20 referenced herein are attached to the Declaration of Dr. Aaron G. Filler.

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involving issued patents are properly resolved in favor of the patentee." *Exxon*, 265 F.3d at 1380.

As explained by the Federal Circuit, "the test for indefiniteness does not depend on a potential infringer's ability to ascertain the nature of its own product to determine infringement, but instead on whether the claim delineates to a skilled artisan the bounds of the invention." *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1340-41 (Fed. Cir. 2005). Where a person of ordinary skill in the art would know how to calculate conspicuity in light of the teachings of the '360 patent, the claims satisfy the requirements of 35 U.S.C. §112, ¶ 2. *See Miles Lab., Inc. v. Shandon*, 997 F.2d 870, 875 (Fed. Cir. 1993) (If the claims "reasonably apprise those skilled in the art of the scope of the invention, §112 demands no more."). A claim term is definite if it is as specific as the relevant science allows. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385 (Fed. Cir. 1986) ("notwithstanding the fact that those calculations are not precise or 'standard,' the claims, read in light of the specification, reasonably apprise those skilled in the art and are as precise as the subject matter permits. As a matter of law, no court can demand more.").

Finally, the Federal Circuit has held that, where the dispute is about testing methodology (as it is here), this dispute is relevant to the question of infringement, not indefiniteness. *Marley Mouldings Ltd. v. Mikron Indus., Inc.*, 417 F.3d 1356, 1360 (Fed. Cir. 2005) ("Accepting Mikron's argument that shaking the wood flour may change its compactness, and thus produce different weight values for a given volume of flour, this argument relates to whether there is infringement of the claims [rather than indefiniteness].").

III.   THE LEVEL OF ORDINARY SKILL IN THE ART IS VERY HIGH.

It appears undisputed that the level of ordinary skill to be used in performing this analysis is as proposed by NeuroGrafix: A medical doctor with an M.D., three years of residency and a 1 year fellowship in neuroradiology or musculoskeletal

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radiology and at least 2 years experience in neuroradiology or musculoskeletal radiology. A person of ordinary skill will also have substantial experience (e.g., 2 years) in the design and physics of an MRI machine, the process regarding how images are generated with it and its limitations. Thus, the indefiniteness analysis must be performed from the point of view of a highly trained and skilled individual.

IV.   THE "CONSPICUITY" TERM IS NOT INDEFINITE BECAUSE A PERSON OF ORDINARY SKILL CAN IDENTIFY A NERVE ON AN MR IMAGE AND THE '360 PATENT DESCRIBES HOW TO RELIABLY AND REPEATABLY SELECT THE REQUIRED REGIONS OF INTEREST.

The Court has already indicated that the "conspicuity" term can likely be construed as the ratio of the average signal intensity of the nerve over the average signal intensity of the relevant non-neural tissue.[2] D.I. 114 at 14. In its Claim Construction Order, however, the Court invited additional briefing regarding two questions: (1) How a nerve is identified on a MR image; and (2) How the regions of interest to be used in the conspicuity calculation are selected. D.I. 114 at 15. With respect to the first question, Siemens does not dispute that a person of ordinary skill in the art can use the teachings of the '360 patent to identify nerves. With respect to the second question, contrary to Siemens' arguments, the '360 patent does in fact expressly describe the process for selecting regions of interest to be used in the conspicuity calculation. Therefore, Siemens' Motion must fail because Siemens has failed to meet its burden of showing by clear and convincing evidence that a person of ordinary skill in the art would not understand how to calculate conspicuity in light of the teachings of the '360 patent.

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[2] Siemens' expert, Dr. Bryan, testified that he disagreed with this calculation. Dr. Bryan's disagreement with the formula for calculating conspicuity is irrelevant in light of the disclosure of the '360 patent.

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A.   It Is Undisputed that a Person of Ordinary Skill in the Art Knows How to Identify a Nerve in Light of the Teachings of the '360 Patent.

The first question raised by the Court in its Claim Construction Order is how a person of ordinary skill in the art would identify a nerve. D.I. 114 at 15. Siemens does not dispute that a person of ordinary skill in the art would know how to identify nerves in an MR image based on their training and experience as well as the disclosure in the '360 patent. As discussed in detail in the expert report submitted by Dr. Brant-Zawadzki, the '360 patent teaches ways to identify a nerve in an MR image. Ex. 2 at ¶¶ 32-34. In particular, using the extensive training and experience of an average radiologist or neuroradiologist (*i.e.*, a person of ordinary skill in the art), gross anatomy shown on an MR image is sufficient to identify a nerve. Ex. 2 at ¶ 31. Similar to attorneys using a treatise, a person of ordinary skill would use a classical or cross-sectional atlas of human anatomy to assist in identifying nerves (as well as other structures) on an MR image. Ex. 3 at 20:22-21:25; Filler Decl. ¶ 4, Ex. 17 (showing an example of a classical and a cross-sectional atlas). The ability to distinguish one type of tissue from another in an MR image is a fundamental skill for practicing radiologists. A radiologist relies on this skill when reading any case study. Ex. 2 at ¶ 38.

Where gross anatomy is insufficient, the '360 patent teaches at least two ways to identify a nerve. First, a person of ordinary skill in the art would look for the presence of a fascicle pattern. Ex. 2 at ¶ 32; Ex. 4 at 27:4-28:26. Fascicles appear as alternating bright and dark portions in the anatomically expected position of a nerve when the invention of the '360 patent is used.[3] *See* Ex. 4 at Fig. 21 (showing cross-section image of fascicle), Fig. 22 (showing longitudinal section of fascicle). They are unique to nerves and distinguish nerves from structures of similar size and shape such as blood vessels, lymphatics, tendons, fat or muscles

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[3] Fascicles appear similar to a checkerboard in cross section and to a set of parallel streamlines in longitudinal section.

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that have no such pattern. Ex. 2 at ¶ 32; Ex. 4 at 27:60-65. Second, in instances
where fascicles are not observable or not sufficient, the combination of diffusion
weighting and fat suppression results in the nerve distinguishing itself from
surrounding tissue. Ex. 2 at ¶ 33; Ex. 4 at 22:33-36).

Thus, it is undisputed that the '360 patent teaches a person of ordinary skill
in the art how to identify nerves on an MR image.

**B.   The '360 Patent, When Read by a Person Having Ordinary Skill
in the Art, Discloses a Definite and Repeatable Method for
Calculating Conspicuity.**

After a person of ordinary skill identifies the nerve, the '360 patent requires
that the person select the appropriate regions of interest ("ROI") to be used in the
conspicuity calculation.[4] In addition to providing a formula for calculating
conspicuity, the '360 patent also defines how to make the required ROI selections.
The types of selections required by the '360 patent are typical tasks for a person of
ordinary skill in the art. Ex. 2 at ¶ 42. For example, Siemens' expert, Dr. Bryan,
has testified that he has selected ROIs of two different structures for comparison of
the signal intensity of the two structures a number of times. Ex. 3 at 43:2-20.   As
shown below, if the selections are done consistent with the teachings of the '360
patent and the knowledge and training of an average radiologist or
neuroradiologist, the calculation of conspicuity is both reproducible and
repeatable.[5]

**1.   The '360 Patent Teaches a Thresholding Process to Select
the Nerve Region of Interest to be Used in the Conspicuity
Calculation.**

Contrary to Siemens' argument, the '360 patent expressly teaches that a
thresholding process should be used to identify the region of interest of the nerve:

First, a thresholding process is used to identify relatively bright
regions of the image potentially representative of nerve. With the

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[4] A nerve identified in one image can be automatically crossed referenced into multiple different
images in the image set using a standard DICOM viewer. Filler Decl. ¶ 6, Ex. 19.
[5] Although Siemens relies on Dr. Bryan's testimony that there are many methods of choosing
regions of interest, Dr. Bryan testified that none of the methods he identified were applicable to
the calculation required by the '360 patent. Ex. 3 at 102:9-19.

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boundaries of these regions established, the intensity of the pixels
associated with each region is evaluated and average image intensities
for the regions are computed.

Ex. 4 at 28:2-28:7; *see also id.* at 21:55-57, 30:65-67.[6]

It is undisputed that conspicuity, in general, refers to the ability to
distinguish one tissue from another. *See, e.g.,* Ex. 5 at ¶ 21; Ex. 3 at 32:16-25; Ex.
6 at 439. It is also undisputed that, in order to meet the conspicuity requirement of
claim 1, 3, 7, 11, 12 and 18, the nerve must be at least 10% brighter than the non-
neural tissue. Ex. 7 at ¶27; Ex. 8 at 55:10-15; 58:12-19. Because the nerve in an
infringing image is brighter, the patent specification expressly discloses a
"thresholding process" for choosing the largest possible portion of the identified
nerve, while excluding artifacts. Ex. 4 at 27:66-28:7; *see also id.* at 21:55-57,
30:65-67 (describing using a threshold process to identify boundaries of the nerve).
Even Dr. Bryan, Siemens' expert, admits that this thresholding process can be used
to "select any bright signal." Ex. 3 at 75:14-17. Although this disclosure has been
pointed out to Siemens (*e.g.,* Ex. 9 at ¶ 21), Siemens has chosen to ignore this
express disclosure in its Motion.

In particular, the disclosed thresholding process involves starting at a bright
area of the identified nerve. Ex. 4 at 30:59-67, Filler Decl. ¶ 7, Ex. 20 at pane B.
The threshold level is then lowered until it encompasses as much of the identified
neural tissue as possible. *See* Ex. 4 at 30:59-67, Filler Decl. ¶ 7, Ex. 20 at pane C.
When the threshold is level is set too low, the thresholding algorithm will grow too
large and include non-neural tissue. *See* Filler Decl. ¶ 7, Ex. 20 at pane D. As
with the selection of other types of structures in an MR image, a person of ordinary
skill in the art will exclude errant pixels due to artifacts such as partial volume

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[6] As the absolute signal intensity of structures on an MR image varies with each image, the
inventors could not have defined a specific threshold. A person of ordinary skill, however,
would understand how to select the appropriate threshold for a particular image. (see
McEldowney Decl. ¶ 6, IND5, figure 10) (showing standard tool from a DICOM image viewing
for performing the "thresholding analysis" described in the '360 patent).

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averaging. Ex. 9 at ¶ 21, Ex. 3 at 88:16-89:11).[7] The result will be a consistent
region of interest for the nerve.[8] *See* Filler Decl. ¶ 7, Ex. 20 at pane C.; Ex. 9 at ¶
21. A person of ordinary skill in the art knows how to identify the appropriate
threshold level using this method because, if the threshold level is set any lower, it
will include non-neural tissue as well as artifacts. Ex. 20. Thus, the '360 patent
indicates a precise as possible method for selecting the appropriate ROI within the
nerve. *See Hybritech*, 802 F.2d at 1385.

Although a specific process for selecting a nerve is disclosed in the '360
patent, a person of ordinary skill also understands that there could be other less
time consuming, but equivalent, methods for choosing a region of interest for a
nerve. For example, in cross-sectional images, such as Fig. 14d or Fig. 20 of the
'360 patent, nerves typically have a circular or oval appearance. Ex. 3 at 65:21-
66:3; 67:2-9. It simply requires using the built-in tools to select the tissue known
to be nerve and not artifact.[9] Ex. 3 at 67:21-68-3. As another example, a person of
ordinary skill would also know that representative regions of interest could also be
used when the signal intensity of the identified nerve is relatively homogenous, the
radiologist will select a representative portion within the nerve.[10] Ex. 2 at ¶ 43; Ex.
10.

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[7] Partial volume average refers to the imaging phenomenon where a pixel is representative of the
average signal intensity of two or more structures. Ex. 3 at 63:17-64:2. This will occur, for
example, when a nerve is leaving the plane of the image or at the edge of a nerve. Ex. 3 at 63:3-
7.
[8] Siemens might argue that there might be small variations in the total area of the nerve identified
in the thresholding process depending on the number of significant digits used in defining the
threshold level. Because the region of interest is an average of all selected signal intensities, any
small variation in the selected region of interest created using the thresholding method should not
have a significant effect on the average signal intensity of the nerve. Siemens has provided no
evidence to the contrary.
[9] While there might be some variation in the neural tissue selected, the fact that the signal
intensity is averaged greatly lessens the effect of these minor variations in the total neural tissue
chosen.
[10] Because the signal intensity is relatively the same, the average signal intensity will not change
meaningfully if different sizes and shapes of selected regions of interest are used. Ex. 3 at 49:8-
13.

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Thus, contrary to Siemens' argument, the selection of the region of interest for a nerve is expressly taught by the '360 patent and is not indefinite.

2.   The '360 Patent, in Light of the Knowledge of a Person of Ordinary Skill in the Art, Teaches How to Identify the Appropriate Non-Neural Tissue and Select a Region of Interest Within the Non-Neural Tissue.

The asserted claims of the '360 patent, when viewed in the context of the teachings of the '360 patent and the extensive knowledge and training of the person of ordinary skill, also teach a definite and repeatable method for selecting the appropriate non-neural tissue to use for the conspicuity analysis. *See supra.* The claims require two different categories of non-neural tissue be used for the conspicuity analysis: (a) Claim 18 and its dependent claims require conspicuity to be calculated using "any adjacent non-neural tissue;" and (b) Claims 1, 3, 7, 11 and 12 and their dependent claims require the use of "the non-neural tissue."

As shown below, the '360 patent sufficiently describes to a person of ordinary skill the size and shape of the region of interest to be selected for use in the conspicuity calculations. Given that the '360 patent is applicable to images of the entire body, it is not possible to provide any more specific description than the description provided below. Contrary to Siemens' argument, the selection of regions of interest of non-neural tissue is as described as specifically as the science will allow. It is not indefinite. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385 (Fed. Cir. 1986).

a.   The Selection Of "Any Adjacent Non-Neural Tissue" In Claim 18 Is Definite And Repeatable.

Claim 18 requires that the nerve have a conspicuity of more than 1.1 times "that of *any adjacent* non-neural tissue." Ex. 4 at claim 18 (emphasis added).[11] The file history for the '360 patent further clarifies that the appropriate adjacent non-neural tissue for the conspicuity calculation is the brightest adjacent non-

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[11] The plain meaning of adjacent as "next to" is unquestionable. *See, e.g.*, Ex. 11 at 27-28 (Claim Construction Order in *Sharper Image Corp. v. Honeywell Int'l, Inc.*, Case No. C 02-4860 CW (N.D. Cal.) construing "adjacent" as "next to one another").

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neural tissue. Ex. 12 at 12 (distinguishing Figure 20 in the Hajnal reference because the surrounding fat was much brighter than the nerve; therefore, "it is clear that the conspicuity of the sciatic nerve is not greater than that of the surrounding fat"); Ex. 13 at 9 (same). Consistent with the intrinsic evidence, Dr. Brant-Zawadzki testified that a person of ordinary skill in the art would select the brightest adjacent non-neural tissue, just as the inventors discussed in the file history. Ex. 2 at ¶ 38.

Siemens attempts to manufacture an ambiguity by disputing that a person of ordinary skill in the art will not know how much of the adjacent non-neural tissue to select. Docket No. 135-1 at 12. Claim 18, however, does not limit the amount of tissue to be selected. Instead, the claim explicitly requires using the "adjacent tissue." Thus, as Dr. Brant-Zawadzki testified, a person of ordinary skill in the art would know to select the entire structure. *See* Ex. 2 at ¶ 43. If the adjacent non-neural tissue is homogenous (that is, has a relatively consistent signal intensity), a person of ordinary skill knows that selecting a representative portion of the non-neural tissue is sufficient. Ex. 2 at ¶¶ 42-43. Therefore, despite Siemens argument, no such ambiguity actually exists. The region of interest will be the representative portion of the brightest adjacent non-neural tissue.

b.   The Selection of "the Non-Neural Tissue" in Claims 1, 3, 7, 11 And 12 Is Also Definite and Repeatable.

The specification of the '360 patent teaches a person of ordinary skill in the art the appropriate region of interest to use to represent the non-neural tissue to be used in the conspicuity calculation for claims 1, 3, 7, 11 and 12. The patent teaches that the average signal intensity of all of the non-neural tissue from approximately 2 centimeters around the nerve should be used in the conspicuity calculation. *See* Ex. 4 at 27:29-35; Filler Decl. ¶¶ 2-3, Exs. 15 & 16.

In particular, in the section entitled "Fascicle Identification and Nerve Enhancement," the '360 patent discloses:

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> Images from the second series were post-processed by selecting (manually) an ***elliptical region of interest, approximately two cm in diameter***, around the sciatic nerve in each of the sections. The region of interest was selected to exclude blood vessels, without requiring the use of the more analytically complex vessel suppression features described above.

Ex. 4 at 27:29-35 (emphasis added). In other words, the '360 patent discloses that the non-neural tissue of interest in this invention is only the non-neural tissue approximately 2 centimeters around the nerve. This is the tissue of interest because, if the nerve has the conspicuity required by claims 1, 3, 7, 11 and 12, the resulting image can be subjected to a maximum intensity projection algorithm to generate a neurogram. *See* Ex. 4 at 27:36-43; *Id.* at 11:53-59, 21:48-54 ("high nerve conspicuity" is required to construct a neurogram according to the '360 patent). One of the primary purposes of the '360 patent is to disclose a neurography system "for generating diagnostically useful images of neural tissue (i.e., neurograms)." Ex. 4 at Abstract. Because the patent expressly limits the construction of the neurogram to using the 2 centimeters surrounding the nerve, a person of ordinary skill understands that the conspicuity analysis is also only concerned with the non-neural tissue within approximately 2 centimeters of the nerve.

The teaching of the '360 patent to use a region of interest surrounding the nerve is also consistent with the existing procedures used in calculating conspicuity for other purposes. Indeed, the concept of using an approximately 2 centimeter ring around the area of interest to calculate conspicuity was used in one of the very first articles to define the concept of conspicuity in the field of radiology. *See* Ex. 6 at 439-40 (conspicuity of chest lesions was calculated by drawing a border around the lesion and taking measurements on both sides of the border[12]).

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[12] The measurements in the Hallberg et al. article were made in a series of spots because of available technology at the time the article was published in the 1970's. Like using today's technology, however, the measurements were averaged to produce a single averaged measure of density for the tissue being measured.

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And, as discussed above, the amount of the non-neural tissue within the approximately 2 centimeters around the nerve cannot be disputed. It all must be selected. Unlike the language of claim 18, claims 1, 3, 7, 11 and 12 do not limit the conspicuity analysis to "any adjacent non-neural tissue." Instead, the claims refer to the relevant non-neural tissue as a whole. Ex. 4 at claims 1, 3, 7, 11 and 12. A person of ordinary skill, in light of the teachings of the '360 patent, understands that the claims require the selection of the entire non-neural tissue unless it is homogenous and a representative portion can be selected. *See* Ex. 2 at ¶ 43.

Thus, the conspicuity analysis would use a region of interest for non-neural tissue that represents all non-neural tissue located approximately 2 centimeters around the nerve. Filler Decl. ¶¶ 2-3, Exs. 15 & 16. As with its other arguments, Siemens has again failed to show that the selection of non-neural tissue required by claims 1, 3, 7, 11 and 12 is indefinite and its motion for summary judgment should be denied.

> **3.   Once a Region of Interest Is Chosen, the Average Signal Intensity Is Automatically Calculated by Standard MR Image Viewing Software.**

Once the nerve is identified and the boundaries of the appropriate regions of interest are selected by an average radiologist or neuroradiologist, as described above, the average signal intensity of each region of interest is automatically calculated by standard MR image viewing software. Ex. 3 at 93:23-94:3. It can also be calculated manually by averaging the signal intensities of every pixel in the selected regions of interest. These average signal intensities can then be used in the conspicuity analysis.

> **C.   Siemens Has Failed to Meet Its Burden to Show by Clear and Convincing Evidence that the Conspicuity Calculation Taught in the '360 Patent Is Indefinite.**

Siemens' arguments should be rejected because they ignore the method for calculating conspicuity described in the '360 patent and as reproduced above. For

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example, none of the calculations done by Dr. Bryan apply the conspicuity method described in the '360 patent.[13]

Siemens also relies heavily on Dr. Filler's "conspicuity" calculations contained in Figures 5, 6 and 7 of Exhibit A to his rebuttal expert report. Motion at 12. These calculations are irrelevant, however, because although Dr. Filler did perform the ratio calculation required by the patent to illustrate his point, Dr. Filler did not attempt to do a formal conspicuity analysis as required by the '360 patent and discussed above.[14] Instead, as the full description provided by Dr. Filler indicates, the purpose of the measurements in Figures 5, 6 and 7 of his rebuttal expert report was to dispute Dr. Moseley's opinion that altering the viewing contrast or window level changes the relative signal intensities being measured.[15] Ex. 7 at ¶ 56. Furthermore, these calculations illustrate that, even with the signal intensity variability exhibited in the rough calculation done by Dr. Filler, the nerve was always significantly more than 1.1 times as conspicuous than the lung. Siemens has provided no mathematical basis as to how these calculations support its argument for the conspicuity of more than 1.1 times argument.

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[13] Additionally, Dr. Bryan's choice of regions of interest to use in his calculations are inappropriate for a number of other reasons, as described by Dr. Brant-Zawadzki. Ex. 9 at ¶¶ 32-33; Ex. 14 at 189:11-191:24. In summary, the regions of interest chosen by Dr. Bryan are not consistent with the regions of interest a person of ordinary skill asked to perform the conspicuity calculation would choose. *Id.*

[14] For example, for the analysis required by claim 18, the muscle is the brightest surrounding non-neural tissue in Figures 5, 6 and 7 of Dr. Filler's rebuttal expert report. McEldowney Decl. ¶ 6, IND5. A person of ordinary skill doing the conspicuity analysis taught by the '360 patent would not have used the lung. Furthermore, also unlike the method taught in the '360 patent, Dr. Filler's informal conspicuity calculation did not select the entire structure (because the lung is not homogenous). Filler Decl. ¶ 5, Ex. 18 (showing the selection of an entire lung). For claims 1, 3, 7, 11 and 12, Dr. Filler did not select all of the non-neural tissue within 2 centimeters of the identified nerve.

[15] In fact, the measurements of the image intensity of the lung emphasize the importance of the teachings of the '360 patent regarding how to choose regions of interest for the conspicuity calculation. For a proper reading of the average signal intensity of the lung (which is a very heterogeneous tissue), the entire tissue must be selected. For the nerve, which is relatively homogenous in the image in Figures 5, 6 and 7, the average signal intensity is relatively similar (within 10%).

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V.   THE COURT SHOULD CONSTRUE THE "CONSPICUITY" TERM AS PROPOSED BY NEUROGRAFIX: "CONTRAST (IN, FOR EXAMPLE, INTENSITY AND COLOR) BETWEEN THE NERVE AND [THE]/[ANY ADJACENT] NON-NEURAL TISSUE IS AT LEAST 1.1 TIMES."

The Court invited this briefing because it was concerned that the conspicuity calculation, as proposed by NeuroGrafix, was subjective and therefore indefinite. D.I. 114 at 14-15. As shown above, the '360 patent teaches a person of ordinary skill in the art a definite and repeatable method for calculating conspicuity. As a result, the Court should construe the "conspicuity" term as proposed by NeuroGrafix: "contrast (in, for example, intensity and color) between the nerve and [the]/[any adjacent] non-neural tissue is at least 1.1 times."

VI.   CONCLUSION

For all the reasons articulated above, Siemens has failed in its burden to show that either of the questions raised by the Court render the '360 patent indefinite. First, it is undisputed that the '360 patent teaches how to identify a nerve on an MR image. Second, the '360 patent in fact teaches a definite and repeatable method for selecting regions of interest to be used in the conspicuity calculation required by claims 1, 3, 7, 11, 12 and 18 of the '360 patent. Contrary to Siemens' arguments, a person of ordinary skill in the art would not be confused as to what portion of the nerve or non-neural tissue to select for use in the conspicuity calculation. Therefore, the Court should deny Siemens' motion for partial summary judgment of indefiniteness.

Dated: September 12, 2011   Respectfully submitted,

RUSS, AUGUST & KABAT

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K&L GATES

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<u>CERTIFICATE OF SERVICE</u>

The undersigned hereby certifies that all counsel of record who are deemed to have consented to electronic service are being served with a copy of this document via the Court's CM/ECF system on September 12, 2011. Any other counsel of record will be served via First Class U.S. Mail on this same date.

By: /s/ Andrew D. Weiss
Andrew D. Weiss

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